IN THE UNITED STATES DISTRICT COURT.
FOR THE DISTRICT OF NEW JERSEY
Civil No. 04-754 (JCL)

PFIZER, INC.,
PHARMACIA CORPORATION,
PHARMACIA & UPJOHN, INC,
PHARMACIA & UPJOHN COMPANY,
D. SEARLE & COMPANY,
SEARLE LLC (DELAWARE),
SEARLE LLC (NEVADA),
G.D. SEARLE LLC,
Plaintiffs,
v.
TEVA PHARMACEUTICALS USA, INC,
Defendants.

Transcript of
Proceedings
TRIAL, VOL. 4

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Newark, New Jersey
November 16, 2006

B E F O R E: HONORABLE JOHN C. LIFLAND,
UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

GIBBONS, DEL DEO, DOLAN, GRIFFINGER & VECCHIONE
BY: DAVID E. DE LORENZI, ESQ.
And: SHEILA MCSHANE, ESQ.
AND
KAYE SCHOLER
By: LEORA BEN-AMI, ESQ.
BY: DANIEL REISNER, ESQ.
AND: THOMAS FLEMING, ESQ.
AND: JEFFREY HOROWITZ, ESQ.
AND: KRYSTA RYCROFT, ESQ.
For the Plaintiff.

LITE, DE PALMA, GREENBERG & RIVAS
BY: MICHAEL E. PATUNAS, ESQ.
AND
GOODWIN PROCTER
BY: THOMAS CREEL, ESQ.
AND: DONNY VERMUT, ESQ.
AND: KEITH ZULLOW, ESQ.
AND: CHRISTOPHER RIES, ESQ.
AND: ANNEMARIE HASSETT, ESQ.
For the Defendant.

By MR. CREEL:

Q. Dr. Trummlitz, in your expert report you refer to an acylsulfonamide. What is the significance of what on your expert report?

A. Okay. Acylsulfonamide. Acylsulfonamide might be transformed into a sulfonamide.

What I was trying to explain is that this is not as what an expert or a person of ordinary skill in the art would have wanted. He would say okay. It is within my picture. I can explain this one example number 14 because it will be active in its active form.

Q. In changing things on the podium, my original questions were misplaced somewhere.

Going back to the upper left-hand corner, the SO 2 groups, why would a person of ordinary skill select one versus the other?

A. Okay. There are several arguments. One is the '196 Merck patent application. In this patent application we have two major groups. These are the methyl sulfonyl group and the sulfamyl group. So we have two.

Now, there are other considerations. We have to take into account that we are using a pyrrazole and in case we are using a pyrazole as a heterocycle, we learn from all the Fugisawa compounds which are included in the '142 patent are methyl sulfonyl compounds. This type. And in order to

avoid any patent problems one would choose the one or prefer the one which is not covered by the '142 patent.

Therefore, we would go to this one. There are additional --

THE COURT: Which one?

A. To the sulfamyl group.

THE COURT: You say this one, the record does not show which one you are talking about.

A. Sorry. I will name them.

THE COURT: Which one again?

A. The sulfamyl group, he would select because this one is not covered within the '142 patent.

Q. Let me also suggest maybe, Dr. Trummlitz, that those words sound very similar. Would it be helpful to refer to that as the SO 2 group with the carbon or the SO 2 group with the nitrogen. Perhaps that would be easier for the record.

A. I think it is quite clear, it would be a definition which everybody could see and could understand. If it is acceptable, yes, I could do it this way.

Q. Thank you. Please. Were you finished?

THE COURT: The one with the nitrogen is the sulfamyl?

THE COURT: Correct.

A. And the one with the carbon is the methyl sulphonyl.

A. Sulfamyl is more direct. It is different wording. I

figure on the upper left-hand with at the bottom 1, 5. That is what he has been talking about.

THE COURT: Thank you.

A. I have drawn a second structure which is right upper side of the chart. We have again the important substituent in this position up here. And we have the second substituent here.

Now again we have to look for the substituents, which is the nitrogen one. Nitrogen becomes number 1. Because this one is the nitrogen which has the substituent. Number two is the second nitrogen. We are following the number 3, 4,5.

This one, because the important substituent for our discussion is direct one, we call this one the 5,1.

Q. For the record, what Professor Trummlitz or Dr. Trummlitz has drawn is in the upper right corner of trial exhibit, court exhibit 7, labeled 5,1?

Q. Is there any other reason why you picked the pyrazole?

A. Okay. Pyrazole has been taken because it is not covered within the '196 application. There are good examples within the '142 patent, and when one are choosing the SAM group, then it is preferable to use a heterocycle like the pyrazole group.

THE COURT: Could you go over that again? I heard what you said but I am afraid I didn't understand it.

information about this type of heterocycle from the patent. Pyrazoles are used in the patent. They are used in other structures, in other nonsteroidal antiinflammatory groups. It is a group which is well known.

Q. You said that here are pyrazoles in the Fugisawa '142 patents, correct?

A. Yes.

Q. So you did pick pyrrazole. Why did you pick the pyrazole for the combination you are talking about, the Merck '196 and the Fugisawa?

A. I picked the pyrazole because we have good examples with the sulfone group within the '142 patent. There are good descriptions, there are interesting compounds, they show good activity. And a person of ordinary skill in the art would not take automatically the same both groups, the pyrazole and the sulfone group. He would like to look into an area which is not covered and the area is not covered by using a pyrazole and using a SAM group which is shown here, SO 2 NH 2.

Q. Do you have an understanding of the term freedom to use?

A. Yes.

Q. Does this play any part at all in the combination you are talking about now?

A. Medicinal chemist has to take into account several of the patent aspects. And he should not infringe a patent of a

competitor company, that is one important point. The other point is from his compounds, it is preferred that they are patentable.

Q. So which, if any, of the substitutions you have on the board there were made for freedom to use purposes?

A. For freedom of use purposes, the SAM group has been chosen, and pyrazole.

Q. Why?

A. The combination.

Q. Why was the SAM group chosen for freedom to use purposes?

A. Yes.

Q. Why was it?

A. Because this SAM group is not covered by the '142 patent.

Q. Why was the pyrazole chosen for freedom to use purposes?

A. The pyrazole we have to look what is known about pyrazoles containing already SAM group. And in the '196 patent we have, this SAM group already described, and if one would use -- I just lost a little bit.

In the '196 application there is no use of the pyrazole, of this part of this heterocycle. In the '196 we don't have examples of this, and therefore, you have freedom of use by using a pyrrazole in view of the '196 patent

A. Yes, I heard about this.
Q. Which of those two has a higher COX-2 selectivity?
A. Okay. There are, because both compounds are so well known, many, many types of literature available on, a lot of test systems. But there is agreement or anybody would say okay. Rofecoxib is a compound which is more selective. Generally, people are talking about the fact of two or three. So so it is the activity, the selectivity of both is higher by a factor of 2 to 3, between 2 and 3.
Q. What is the brand name for rofecoxib?
A. Yes, it has been marketed as Vioxx.
Q. When you were given the selectivity ratios were you talking about Vioxx as opposed to rofecoxib in the laboratory setting, or do you know? I don't know?
A. No. Vioxx is, is, the chemical name of Vioxx is rofecoxib. Therefore, I compared the compounds, rofecoxib versus Celecoxib or the trade names Celebrex versus Vioxx.
Q. Was rofecoxib disclosed to a person having ordinary skill in the art prior to August 1, 1993?
A. Okay. I looked through the patent application, '196, and the patent, '995. Rofecoxib is an example compound in the patent '995. It is not named as an example. It, the chemical name is not included in the '196 application.

Therefore, the roots, the overreaching of the refocoxin is the '995, it was disclosed in the '995 patent.